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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,210	11/25/2003	Herve Bouchard	ST01018G1 US CNT	5501

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EXAMINER

DAVIS, ZINNA NORTHINGTON

ART UNIT PAPER NUMBER

1625

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,210	BOUCHARD ET AL.	
	Examiner	Art Unit	
	Zinna Northington Davis	1625	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) no drawn to the examined subject matter is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 16-29-38 is/are rejected.
- 7) ☒ Claim(s) 9 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2/17/04</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Claims 1-38 are pending.
2. In the response filed December 16, 2004, Applicants have elected the compound of the species of the compound of claim 1 wherein n, m, p and q are 1, nitrogen containing aromatic ring is a quinoline optionally substituted, the aromatic and nonaromatic ring is a quinoline optionally substituted, R₃ and R_{3'} are hydrogen or C₁₋₄ alkyl, and the distribution agent is a 5- or 6-membered heterocyclic radical. The preferred compound is bis[(4-dimethylamino-2-methylquinoline-6-yl)amido]-2,5-thiophenedicarboxylic acid.

Response to Applicants' Remarks about the Lack of Unity

Applicants state that the IPER does not comment on lack of unity of invention. The instant claims 1-38 in the present application are by far modeled after the original claims 1-36 and have been presented more suitably in the US format. Therefore, it is respectfully submitted that similar standards as used in the international examination be used in the instant application and this imposition of restriction be withdrawn.

It is the Examiner's position that:

- Unity of Invention does exist.
- The compounds according to claim 1 are independent and patentably distinct.
- While the IPER has been established, the examination of the claims in the US Office is independent of an international report.

Applicants state the search of all of the claims 1 to 38 should not impose any undue burden on the Examiner. In support of our assertion, Applicants point out that the

compounds of formula as recited in claim 1 encompasses a Markush grouping all of which can be searched together. Further, the independent claims 31 and 38 recite pharmaceutical composition and method of treatment incorporating a compound of formula (1), which is also recited in compound claim of 16. Accordingly, it is respectfully submitted that the examination of all claims 1 to 38 should not impose any undue burden on the Examiner.

It is the Examiner's position that:

- The compound of claim 1 includes an improper Markush grouping.
- The chemical compound, pharmaceutical composition and method of use will be grouped together.
- The examined compound will be recited below.

Applicants state the products and the related use claims should be rejoined pursuant to MPEP 821.04.

It is the Examiner's position that:

- The claims were never restricted.
- The chemical compound, pharmaceutical composition and method of use will be grouped together.

Finally, Applicants state that this restriction imposes an undue expense on the Applicants and discourages Applicants to maintain a plurality of patents, which is against the constitutional intent to promote the progress of science and technology and thus against the public policy. For these reasons and for the reasons advanced above Applicants request the Examiner to consider and withdraw this restriction requirement.

It is the Examiner's position that:

- The claims as presented impose an undue search burden on the Examiner.
- The examination and search should to drawn to one patentable invention.
- Based upon applicant's plurality of inventions in one application, it would be against Office policy to examine more than one invention in an application.
- The examiner has considered applicants' remarks and has not found them persuasive.
- The requirement is still deemed proper and is therefore made FINAL.

3. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

4. Claims 1-38 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

5. Claims 1-38 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnish, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group(1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

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In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush groups are p, n, m and q.

6. The examined subject matter is as follows:

A compound of formula I where n, m, p and q are 1; nitrogen containing aromatic ring is a quinoline or pyridine; the aromatic and nonaromatic ring is a quinoline, pyridine, or phenyl; the distribution agent is a triazine group, 5- or 6-membered heterocyclic radical, phenyl, or a diazine group.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 23, 24, 30, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. At claim 1, line 1, it is suggested that the term "general" should be deleted.

B. Claims 1 and 23 are identical.

- C. Claims 1 and 24 are identical.
- D. Claims 30 and 31 should end with only one period. Correction is appreciated.
- 9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 10. Claims 1-8, 10-14, 16-29, and 32-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Plumbe et al (Reference N).

The instantly claimed compounds are disclosed. At pages 1 and 2, see the formula. At page 3, lines 10-12, the compounds are taught to inhibit tumor growth. At pages 4-6, see the examples and claims.

- 11. Claims 1-8, 10-14, 16-18, 23, and 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hiranti et al (Reference U).

The instantly claimed compounds are disclosed. At pages 3331, scheme 1, see the compound 1, 3 and 5.

- 12. Claims 1-8, 10-14, 16-20, 23-29, and 32-38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Denny et al (Reference V).

The instantly claimed compounds are disclosed. At page 136, see entry 54-62 and 84-88. At page 143, see compound 1.

- 13. Claims 9 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

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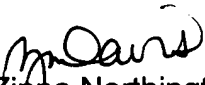
the base claim and any intervening claims to the extent that the claims read on the examined subject matter as recited above.

14. The Information Disclosure Statement filed February 17, 2004 have been considered.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

16. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


Zinna Northington Davis
Primary Examiner
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